Human Subjects System (HSS) (Grantees)

System Version 1.00.02

Document Version 1.1.1

August 23, 2018

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DOCUMENT HISTORY

Date	System Version	Document Version	Description of Change	Author
June 21, 2018	1.0.0	1.0.0	Initial publication of document	eRA Communications
August 14, 2018	1.00.01	1.1.0	Updates to migrated IDR information for CT questions, warning on RPPR if CT indicated and no study is included, and new topic - "How To Change the Application Status and Resubmit".	eRA Communications
August 23, 2018	1.00.02	1.1.1	Added Additional Resources topic	eRA Communications

The most current version of this document will be available on the eRA intranet:
http://era.nih.gov/files/HSS_user_guide.pdf

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1 The Human Subjects System (HSS)

1.1 Purpose

The HSS system is a shared system that enables grant recipients to electronically report and update their data on human subjects and clinical trials to NIH; and for NIH agency staff to monitor and manage the data. HSS replaced the Inclusion Management System (IMS) and all IMS data submitted to NIH by June 8, 2018 was migrated to the new system.

The HSS is automatically populated by human subjects and clinical trial data entered by the principal investigator on the Human Subjects and Clinical Trial Information form in applications submitted for due dates of January 25, 2018 and beyond. This data is then made available to PIs and signing officials through a Human Subjects link that will be available on the eRA Commons Status screen and the Research Performance Progress Report (RPPR).

NOTE: HSS replaced the Inclusion Management System (IMS), used for reporting participant sex/gender, race, and ethnicity information. The Inclusion link no longer appears on the Commons Status page as of June 9, 2018.

1.2 Key Changes

1. NIH migrated enrollment records in IMS to HSS. ***Updates to enrollment records must have been submitted to NIH no later than June 8, 2018 or entered in HSS***. Updates not submitted by June 8, 2018 are not available in HSS and must be re-entered.
2. NIH recipients completing an RPPR (Research Progress Performance Report) will be prompted to access HSS to update inclusion enrollment reports. Recipients may access the system through the Human Subjects link in the RPPR or the eRA Commons Status page.
3. *Section 6: Clinical Trial Milestone Plan* is intended for use in progress reports for competing applications submitted on or after January 25, 2018 and is not currently required unless otherwise noted in the Funding Opportunity Announcement or terms and conditions of award. Recipients should refer to the RPPR Instruction Guide for guidance.
4. The HSS system includes a new interface and workflow. When submitting studies to NIH, Signing Officials will submit all study records associated with an application at one time rather than separately.
5. Participant-level sex/gender, race, ethnicity and age data may be submitted in a CSV file to populate the Inclusion Enrollment Report. Participant level data will be required for applications submitted January 25, 2019 or later. See NOT-OD-116 for additional information.
6. Investigators and signing officials may make study updates or corrections (including just-in-time or off-cycle updates) by accessing HSS through the Human Subjects link in the eRA

Commons Status page. Some changes, including those involving increased risk to human participants, may require prior approval by NIH.

7. Users are currently unable to delegate authority for HSS updates and/or submissions to another user. Delegation authority is expected to be available in a future enhancement of HSS.

1.3 How NIH grantees will use the system

Depending on their roles and privileges, NIH grantees can use the Human Subjects system to:

- Edit existing studies
- Add studies
- Convert Delayed Onset studies

1.4 Resources

Additional resources such as video tutorials, crosswalk, and infographic on the Human Subjects System (HSS) are available at https://era.nih.gov/hss_training.htm.

Additional information about the PHS Human Subjects and Clinical Trials Information form is available at https://grants.nih.gov/policy/clinical-trials/new-human-subject-clinical-trial-info-form.htm.

2.1 Access Human Subjects System (HSS)

The *Human Subjects System* can be accessed by Principal Investigators (PIs) or Signing Officials (SOs) through either the RPPR or through the *Status* screen in eRA Commons

2.1.1 Human subjects information may need to be updated in the following scenarios:

- Post-award for updates to the Research Performance Progress Report (RPPR)
- Pre-award (post review) for just-in-time information or correction of human subjects data
- Off-cycle updates as required in the Funding Opportunity Announcement or terms and conditions of award
- Corrections to human subject data

2.0.0.1 Here is a summary of the ways HSS can be accessed:

- SO: Status tab > General Search screen > Specific Award >Action column > Human Subjects Link
- PI: Status tab > Status — PI Search screen > Status Result — List of Applications/Awards screen > Specific Award >Action column > Human Subjects Link
- Both: RPPR tab > Manage RPPR > Specific Grant > RPPR Menu screen > Edit button > Inclusion Section (G.4.b) > Human Subjects Link

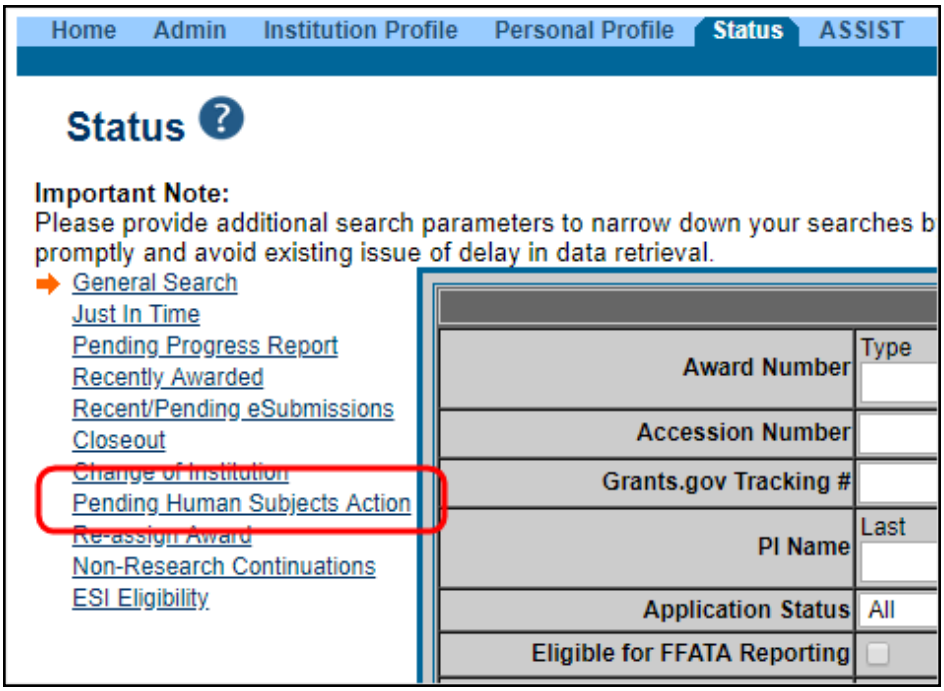
More detailed instructions are below. Each method will result in access, via HSCT Post Submission, to inclusion enrollment reports in regular and delayed onset study records.

2.1.2 To edit an existing study, log into eRA Commons and access the Human Subjects link via the RPPR or Status tabs.

2.0.0.2 Access via Status

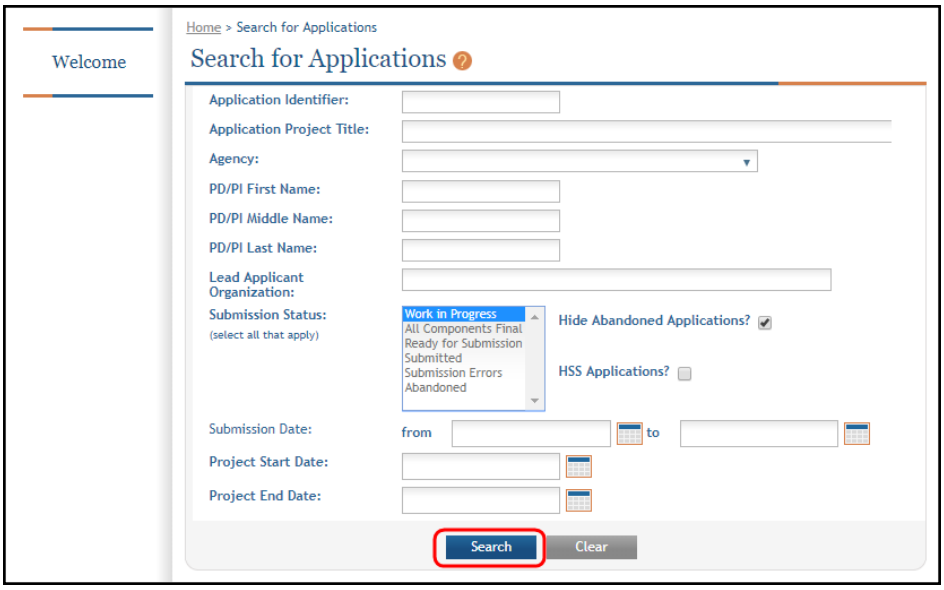
SOs

- SOs will now see a link on the *Status* page for **Pending Human Subjects Action**.

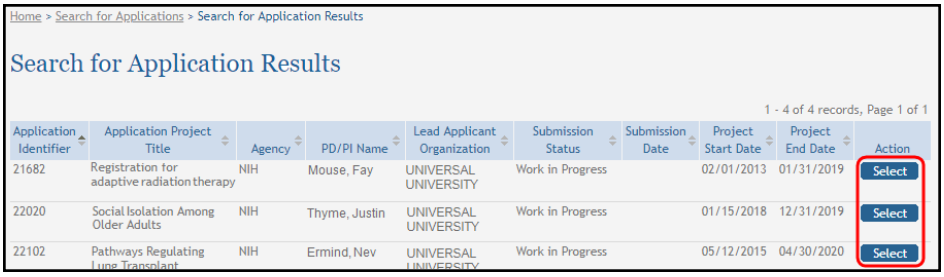


- Select the *Pending Human Subjects Action* link to be taken to the *Search for Applications* screen. On this screen, you may search via a submission status or use additional details to

narrow the search results.

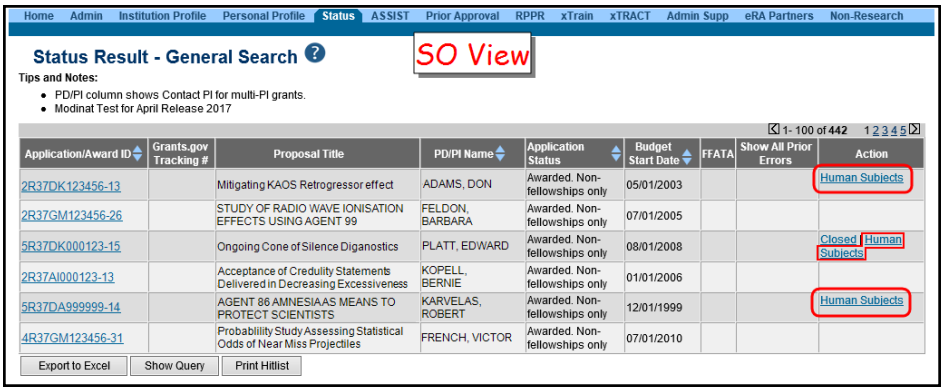


- On the resulting hitlist, click the **Select** button. The application summary page will be displayed.



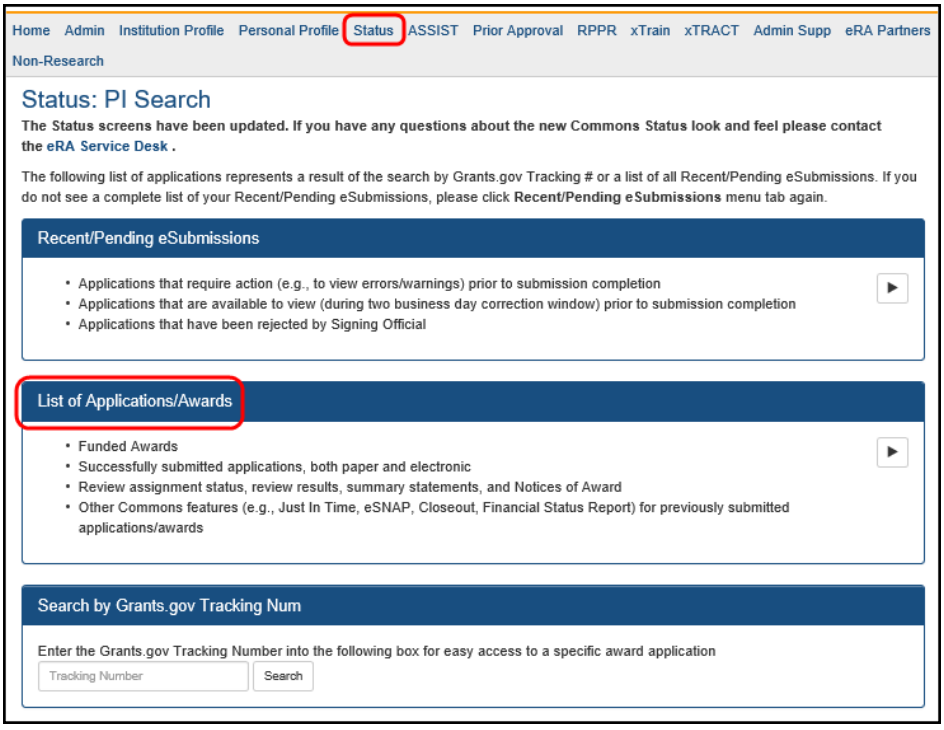
- Additionally, the SO may use the *General Search* on the *Status* screen to produce a hitlist of

applications and then select the *Human Subjects* link in the *Action* column.



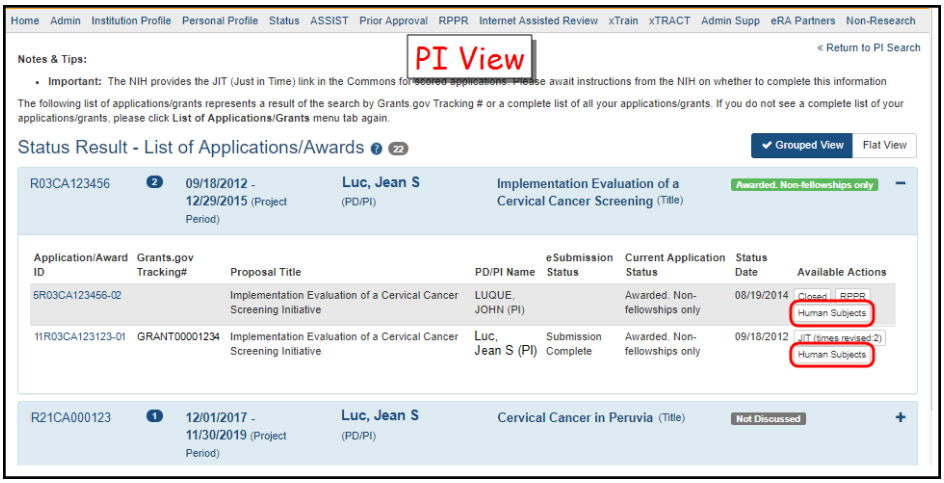
PIs

- A PI can click on the *Status* tab and then on *List of Applications/Awards* to see a list of their applications.



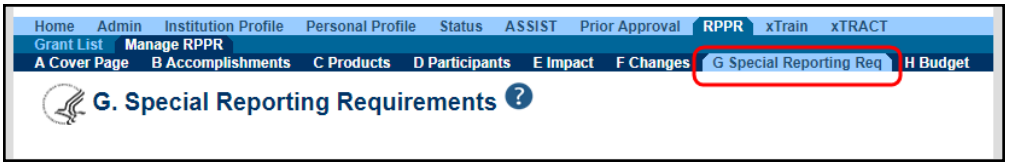
- The resulting hitlist will have a **Human Subjects** button in the **Available Actions** column on those applications with Inclusion Enrollment Reports (IERs). IERs replace the Inclusion Data Records (IDRs) used in the prior inclusion management system.
  Selecting the **Human Subjects** button will open the *Summary* page for that application with

the *HSCT Post Submission* tab available to access the human subjects data.

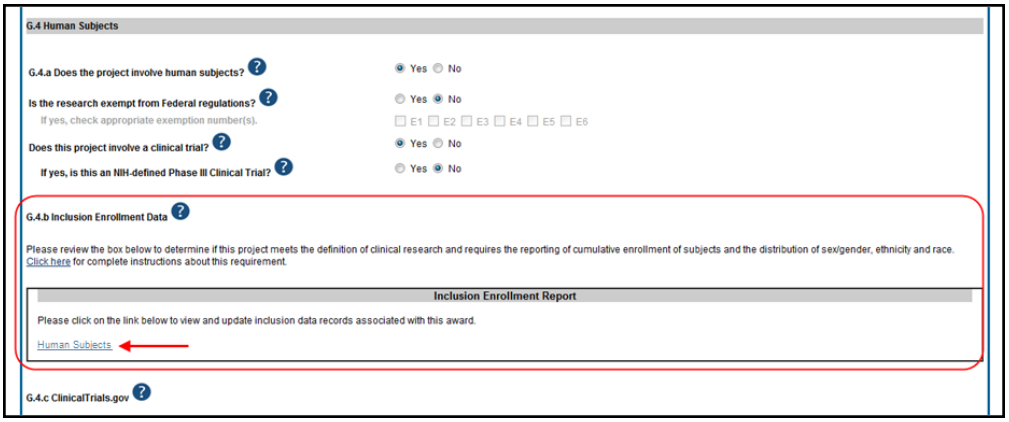


Access via RPPR

To Access HSS via an RPPR, select the *RPPR* tab and then, in the *Edit* view, select the tab labeled, *G Special Reporting Req*.

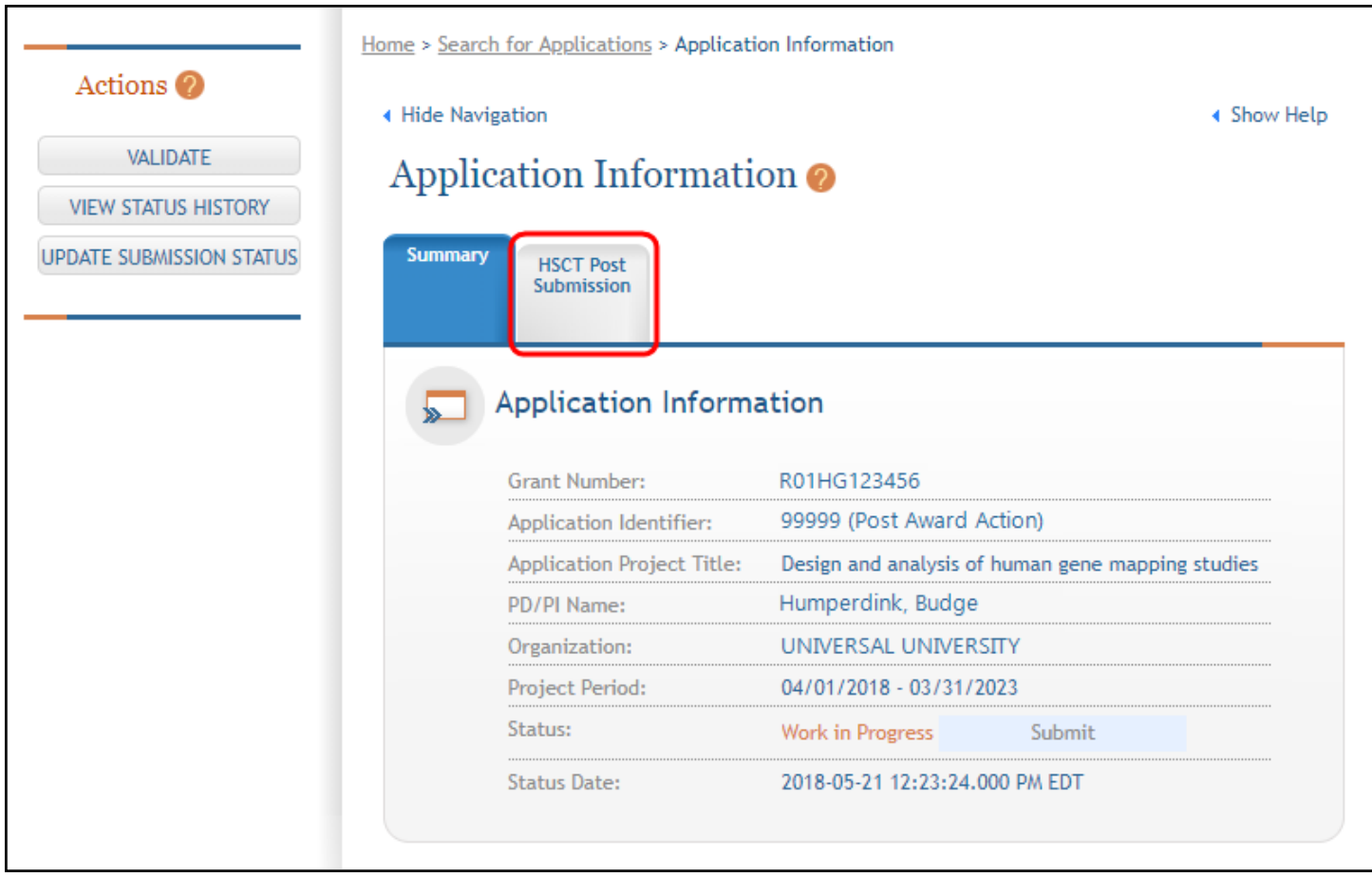


After selecting the *GSpecial Reporting Req* tab, scroll down to section *G.4.b Inclusion Enrollment Data* and then select the link for *Human Subjects*.



The above methods will take the user to the *Application Information* screen and provide access to the *HSCT Post Submission* tab.

Click on the *HSCT Post Submission* tab. This will take you to a *Study Record(s)* screen where all study records and delayed onset studies associated with your grant are displayed.



3.1 Crosswalk Between IMS & HSS

There are differences in the way that inclusion data was accessed and managed in the retired IMS module compared to HSS. Please see this handy resource to figure out the differences.

Crosswalk between the Inclusion Management System and HSS - Word; May 16, 2018

4.1 Editing Studies

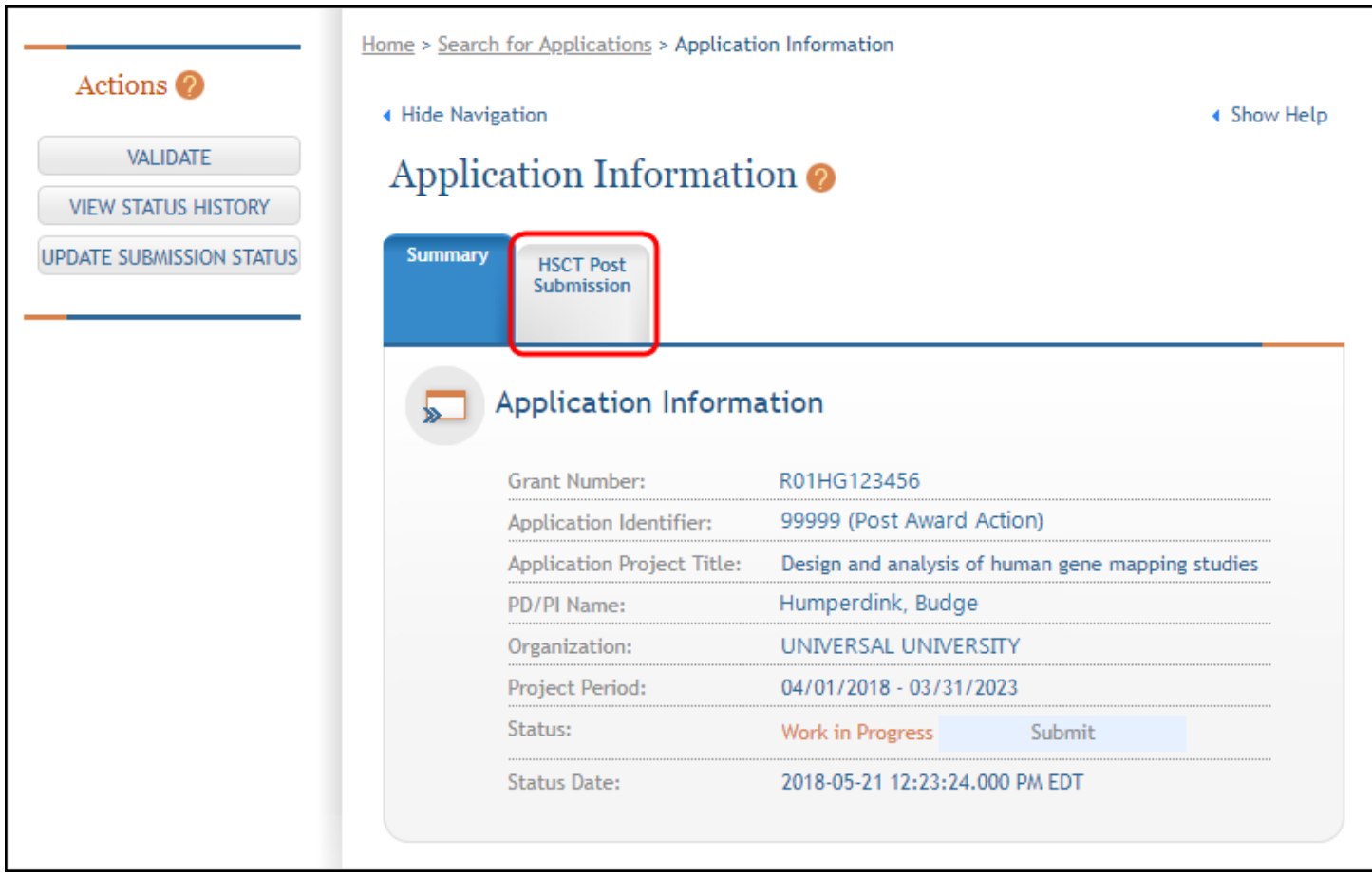
In order to edit study information, the Principle Investigators (PIs) or Signing Officials (SOs) can access the HSCT form using the *Human Subjects* links in either the RPPR or through the *Status* screen in eRA Commons. Refer to Access Human Subjects System (HSS) for details.

4.1.1 Human subjects information may need to be updated in the following scenarios:

- Post-award for updates to the *Research Performance Progress Report (RPPR)*
- Pre-award (post review) for *Just-in-Time (JIT)* information or correction of human subjects data
- Off-cycle updates as required in the *Funding Opportunity Announcement (FOA)* or terms and conditions of award

4.1.2 To edit an existing study, log into eRA Commons and access the Human Subjects link via the RPPR or Status tabs.

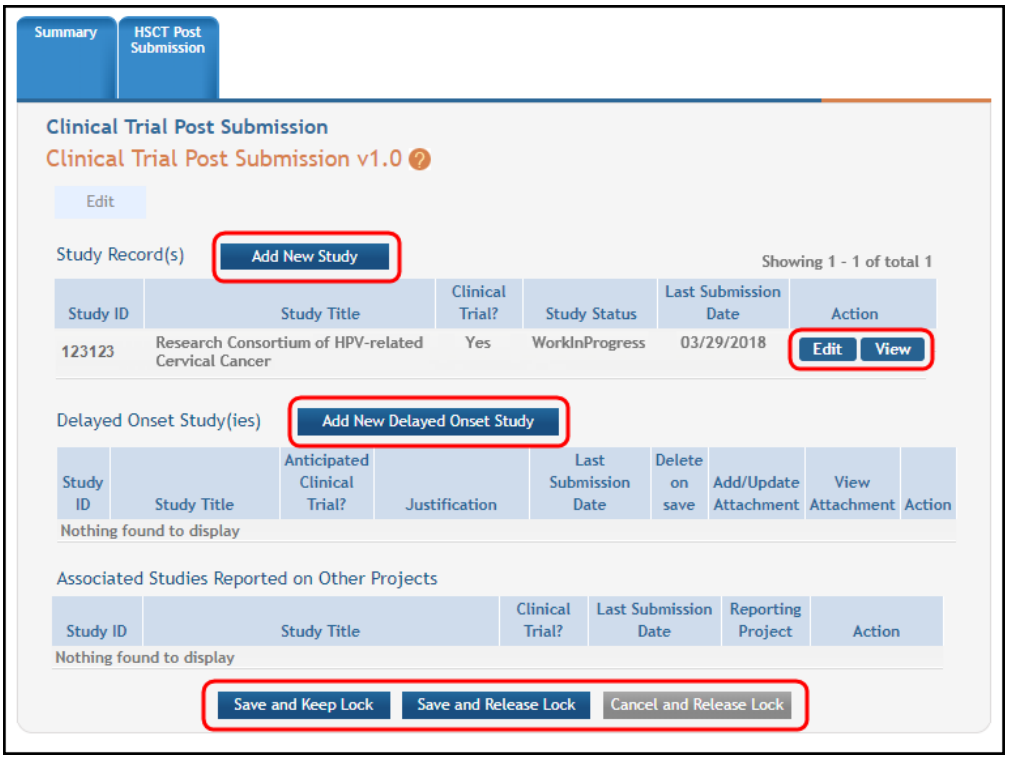
The *Application Information* screen is displayed, showing a summary of your grant. Click on the *Human Subjects Post Submission* tab. This will take you to a Study Record(s) screen where all study records and delayed onset studies associated with your grant are displayed.


Actions
VALIDATE
VIEW STATUS HISTORY
UPDATE SUBMISSION STATUS
Home > Search for Applications > Application Information
Hide Navigation
Show Help
Application Information
Summary
HSCT Post Submission
Application Information
Grant Number: R01HG123456
Application Identifier: 99999 (Post Award Action)
Application Project Title: Design and analysis of human gene mapping studies
PD/PI Name: Humperdink, Budge
Organization: UNIVERSAL UNIVERSITY
Project Period: 04/01/2018 - 03/31/2023
Status: Work in Progress Submit
Status Date: 2018-05-21 12:23:24.000 PM EDT

Click on the **View** button to bring up a study.

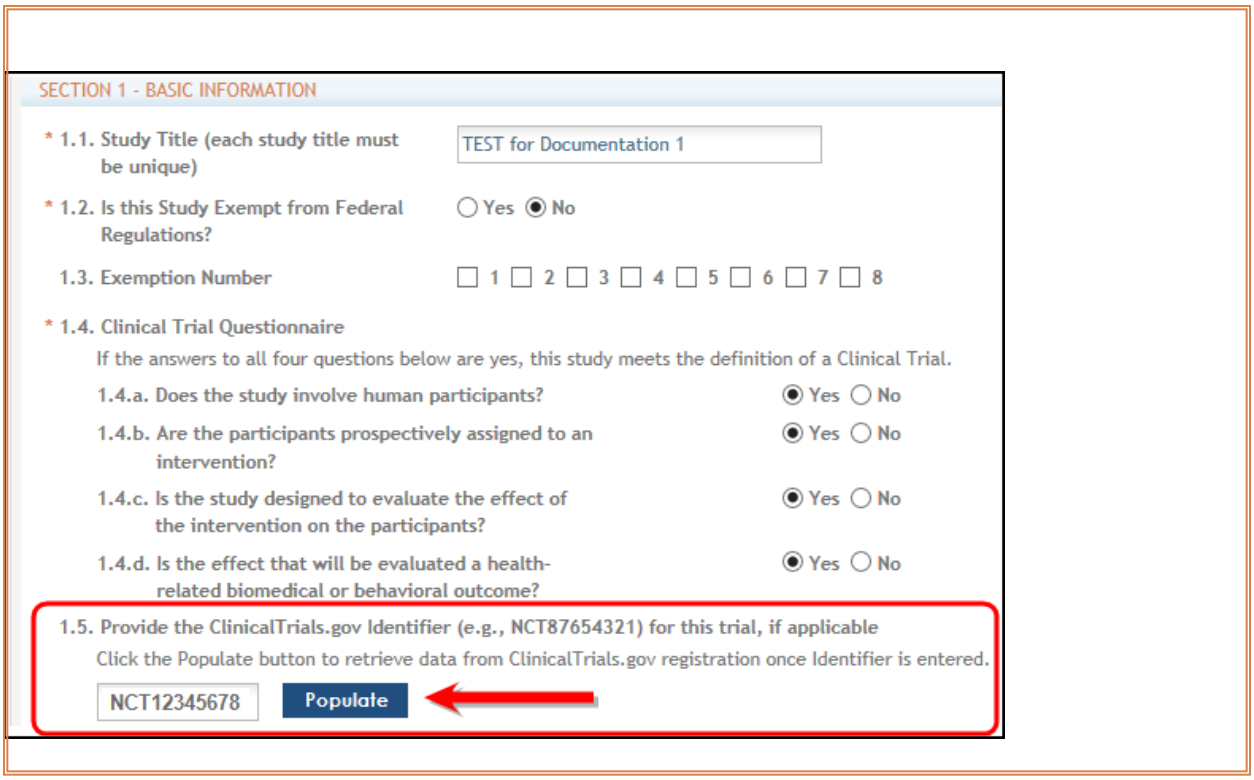
To update the human subjects information on that study, including inclusion enrollment data, click the **Edit** button at the top of the screen.

Now you will see that the existing study has an **Edit** button available and there are additional buttons to add regular or delayed onset studies.



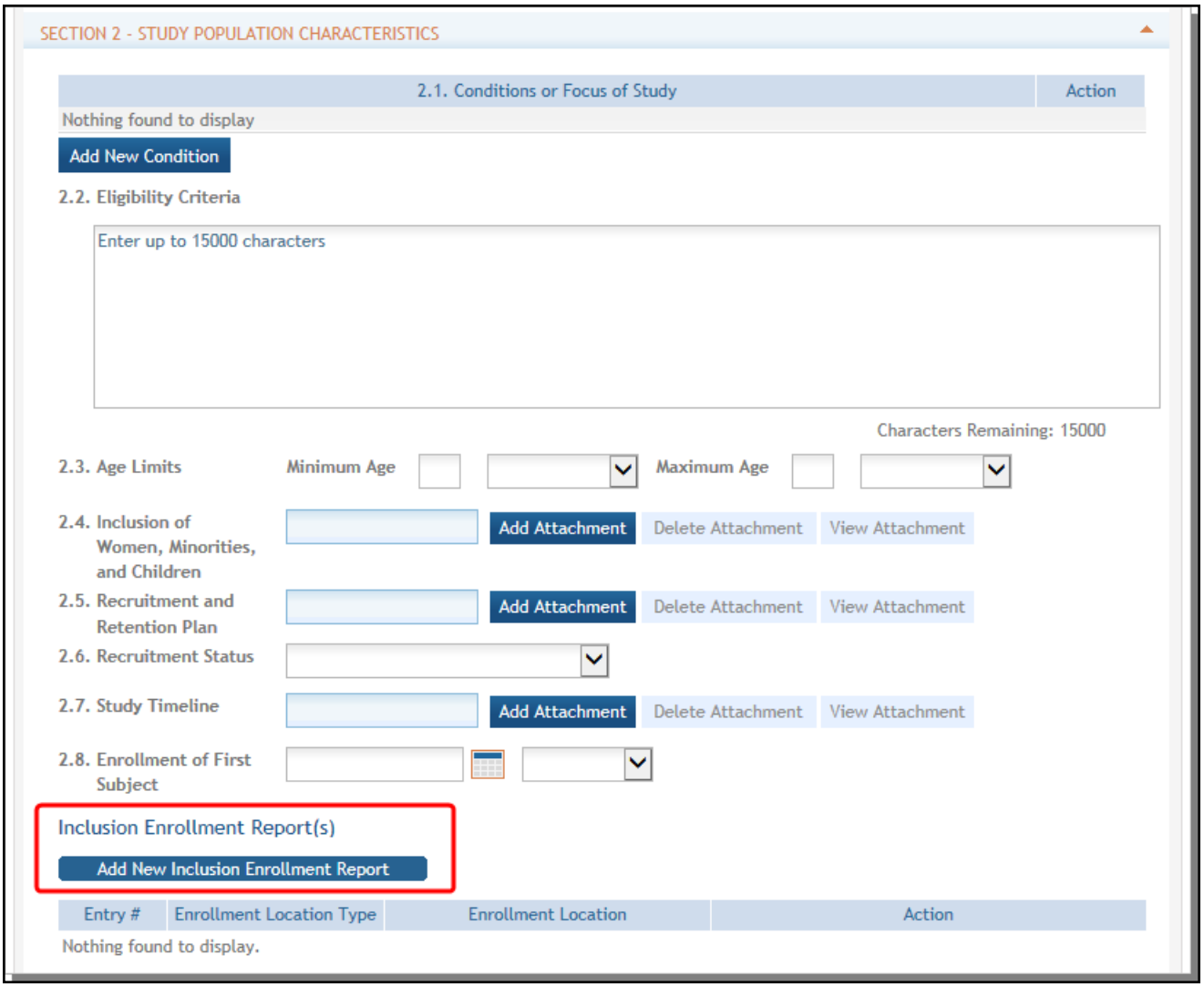
Selecting the **Edit** button for the existing study will open the *Application Information* screen.

IMPORTANT: If the initial competitive segment was submitted on or after January 25, 2018 (i.e. a Forms E application) without a ClinicalTrials.gov Identifier (an NCT number), enter the appropriate NCT number in the field numbered 1.5.
Select the Populate button and the system will do a best effort copy of form data from the official Clinical Trials records.



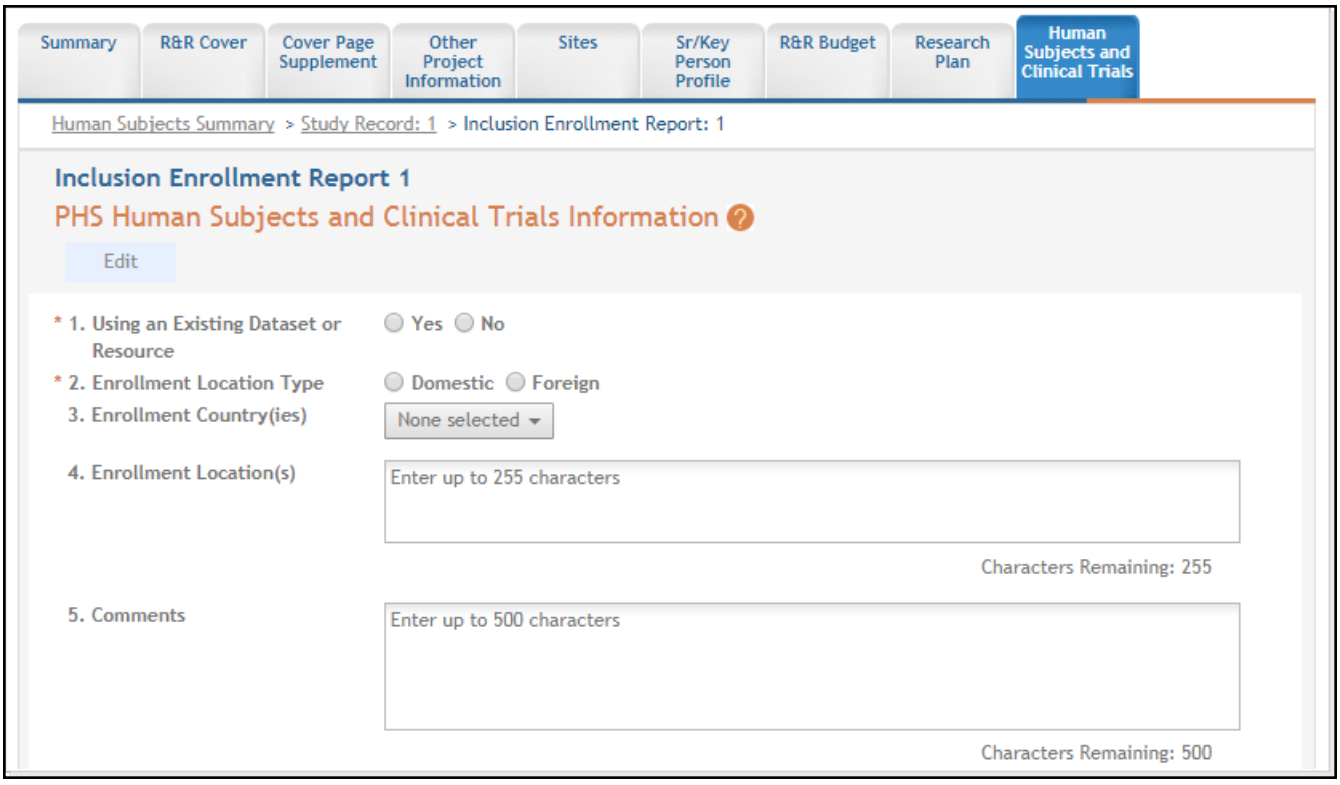
4.1.3 Inclusion Enrollment Report

Standalone PHS Inclusion Enrollment Report forms are no longer used. Instead, data collection for up to 20 *Inclusion Enrollment Reports* has been folded into each *Study Record*. Click on the link in *Section 2* of the *Study Record* screen to initiate the *Inclusion Enrollment Report*.

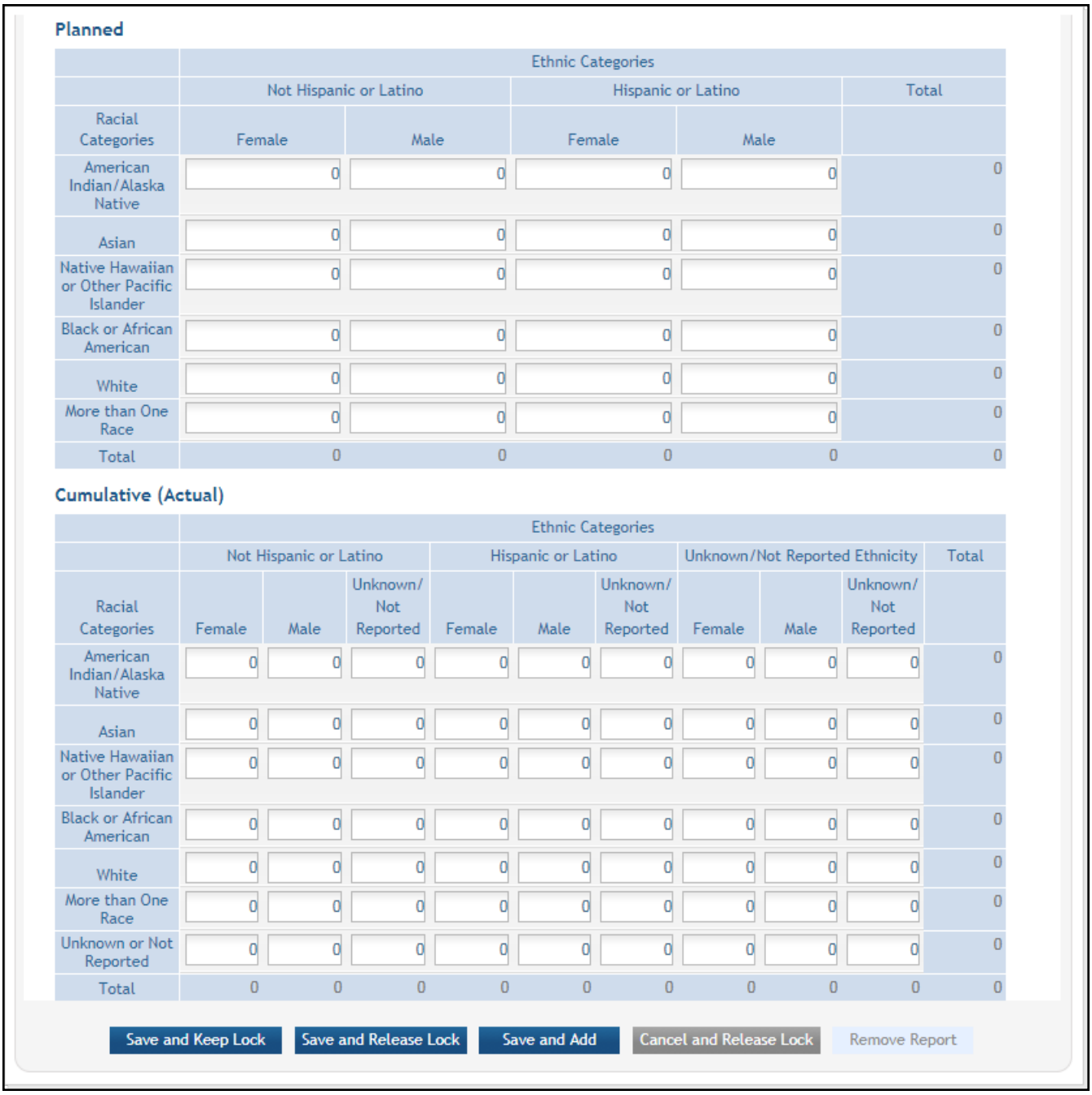


For each *Inclusion Enrollment Report*, applicants will need to indicate whether an existing dataset or resource will be used and whether the enrollment location type is domestic or foreign.

There are also a few optional fields in the report, including a text entry ***Comments*** section.



Planned and *Cumulative* enrollment data collection has been separated into separate tables.



Planned

	Ethnic Categories				
	Not Hispanic or Latino		Hispanic or Latino		Total
Racial Categories	Female	Male	Female	Male	
American Indian/Alaska Native	0	0	0	0	0
Asian	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	0	0	0	0	0
White	0	0	0	0	0
More than One Race	0	0	0	0	0
Total	0	0	0	0	0

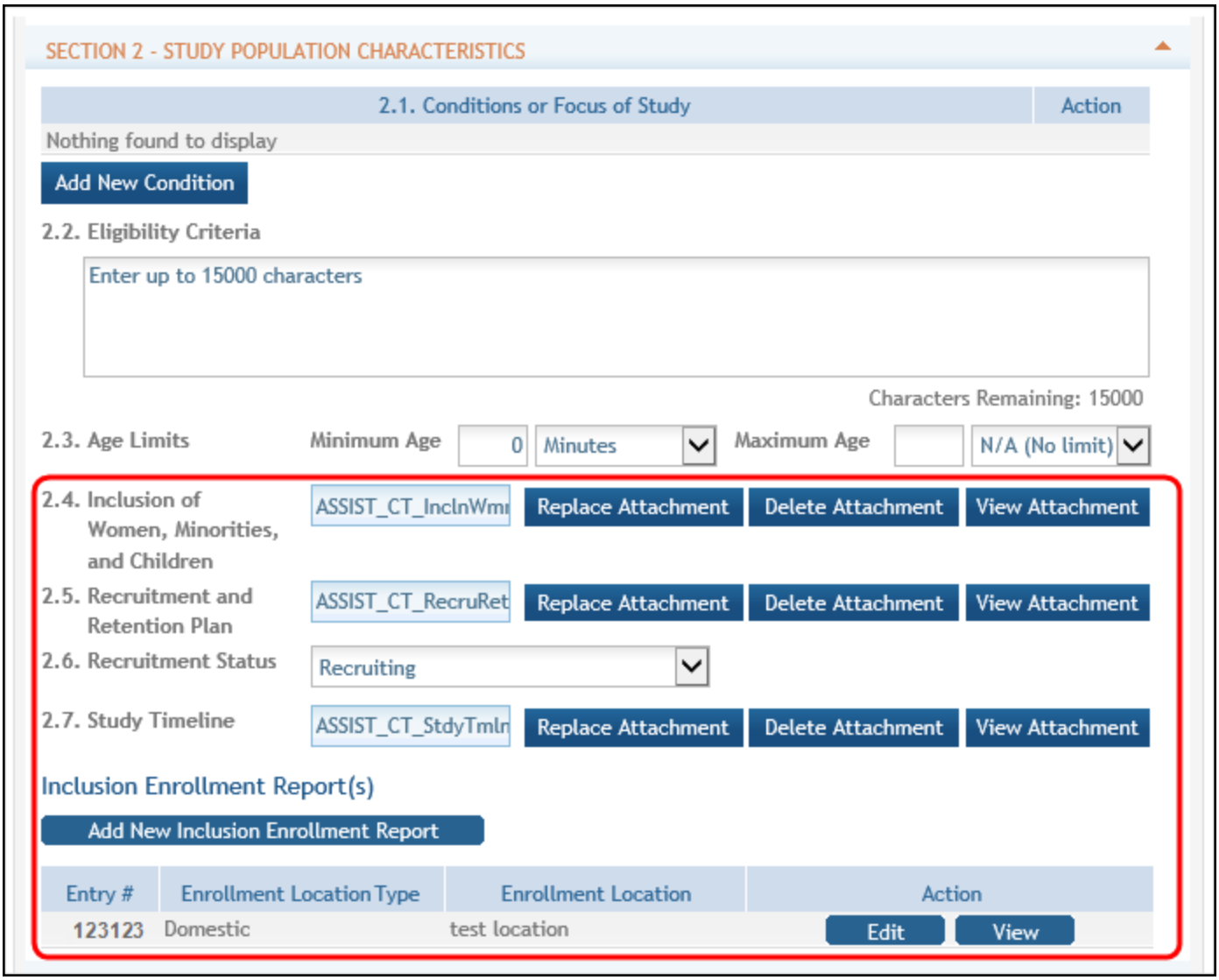
Cumulative (Actual)

	Ethnic Categories									
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			Total
Racial Categories	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Save and Keep Lock | Save and Release Lock | Save and Add | Cancel and Release Lock | Remove Report

4.1.4 Editing Inclusion counts

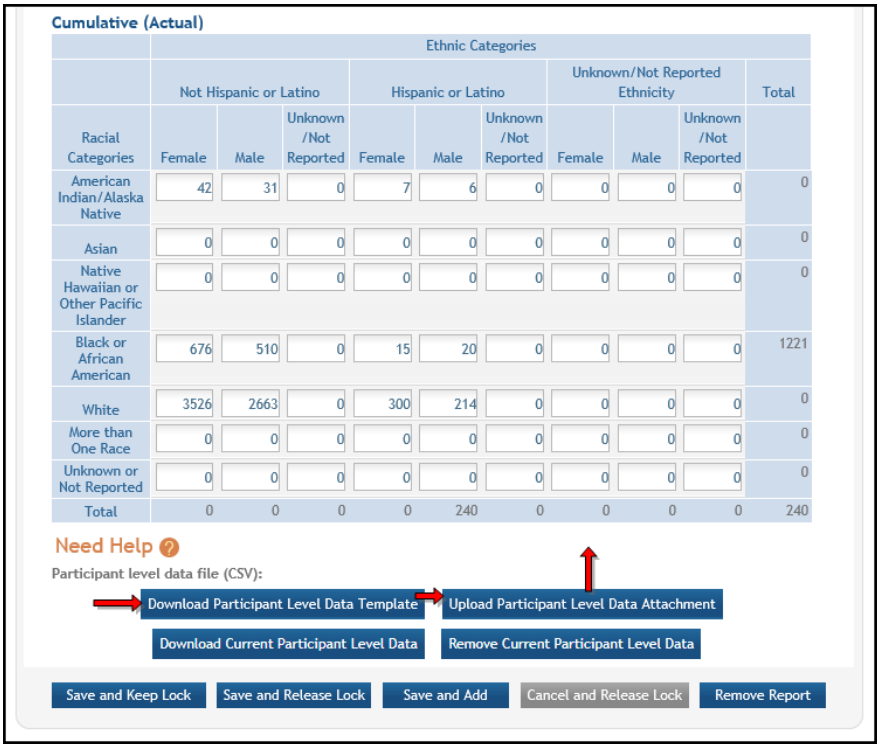
Inclusion data is found at the end of Section 2.



There are two ways to edit the existing Inclusion Enrollment Report (IER) data for Cumulative (Actual) counts:

1. You can update the cells online in the existing report itself.
2. You can download a template for entering participant-level data by clicking on the **Download Participant Level Data Template** button.
   This will download a spreadsheet file in the proper CSV format to be used by the system.
   - Fill the template out with data, save the changes, and then upload the spreadsheet by clicking on the **Upload Participant Level Data Attachment** button. This uploaded data will populate the cells in the report.
   - You can click on the **Download Current Participant Level Data** button to download the file containing the data for your own records.

- If you need to clear the current records, use the **Remove Current Participant Level Data** button.



NOTE:

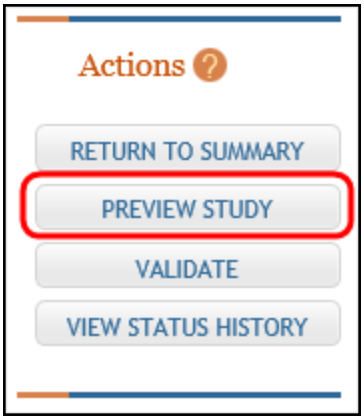
- If you plan to upload the data, you must use the template by selecting the **Download Participant Level Data Template**. This will be a CSV file that can be updated with new totals.
- Once the new totals have been entered into the template and the file has been saved, use the **Upload Participant Level Data Attachment** button to upload the file which will update the Cumulative counts.
- Individual-level participant data on sex/gender, race, ethnicity and age at enrollment will be required in progress reports for competitive applications submitted for due dates on or after January 25, 2019 (See NIH Guide Notice NOT-OD-18-116).

For the Planned counts, the cells must be updated online in the report itself.

Planned

	Ethnic Categories				
	Not Hispanic or Latino		Hispanic or Latino		Total
Racial Categories	Female	Male	Female	Male	
American Indian/Alaska Native	42	31	7	6	0
Asian	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	676	510	15	10	1211
White	3526	2663	300	214	0
More than One Race	0	0	0	0	0
Total	0	0	0	230	230

The entire study can be previewed before submission by clicking on the **Preview Study** button on the left navigational column under Actions.



4.1.5 PI and SO Actions

If the PI is making changes:

- The PI can click the **Save and Release Lock** button to save the changes.
- The submission status changes to *Work in Progress*.
- PI changes status to *Ready for Submission*.
- SO logs into ASSIST, finds the application, and submits it.

If the SO is making changes:

- The SO can click the **Save and Keep Lock** button to save the changes.
- The submission status remains in *Work in Progress*.
- The SO must click the **Save and Release Lock** button to allow the application to have the status changed.
- SO changes status to *Ready for Submission*.
- The *Submit* action becomes active on the *Application Information* page.
- SO clicks on the **Submit** button

Only the SO can submit the application to NIH. The submission sends all updated study records associated with the application to NIH at one time.

Program officials and grant specialists are notified automatically of study changes and can review those changes. Some changes may require prior approval.

NOTE: If the application has been submitted and needs to be placed back into a work in progress status, refer to these instructions to perform this action; https://era.nih.gov/erahelp/ASSIST/default.htm#ASSIST_Help_Topics/5_Preview_Print_Submit/Revise_Application.htm?Highlight=status

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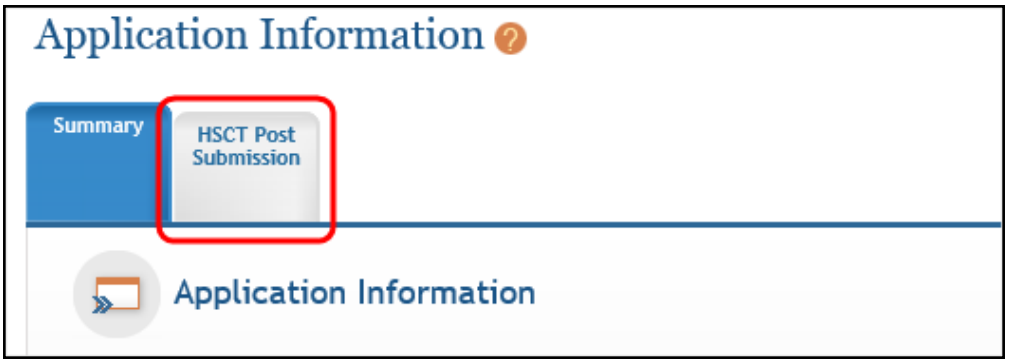
5.1 Adding Studies

After the initial submission of the application, additional studies may be added once the summary statement is released.

Access the *HSCT Post Submission* tab via the *Human Subjects* links in the *Action* column of *Status* or the *Human Subjects* link in section G.4.b in the progress report.



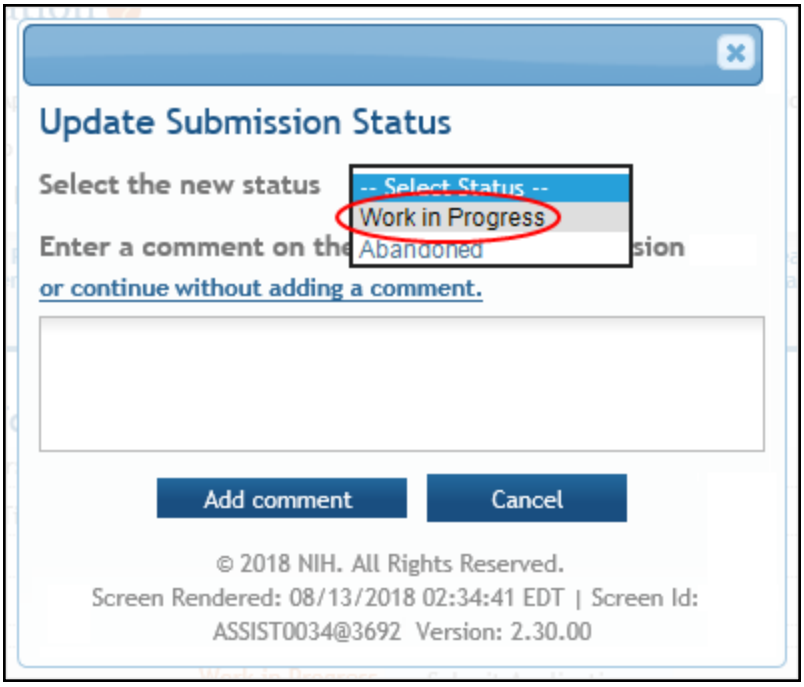
Any study records already submitted will be displayed and may be viewed and buttons to **Add New Study** and **Add New Delayed Onset Study** will be displayed. Click on the appropriate button to add studies.

Once the study has been added be sure to use the **Save and Keep Lock** or **Save and Release Lock** buttons to secure your updates.

5.1 How To Change the Application Status and Resubmit

5.1.1 To revise and resubmit an application:

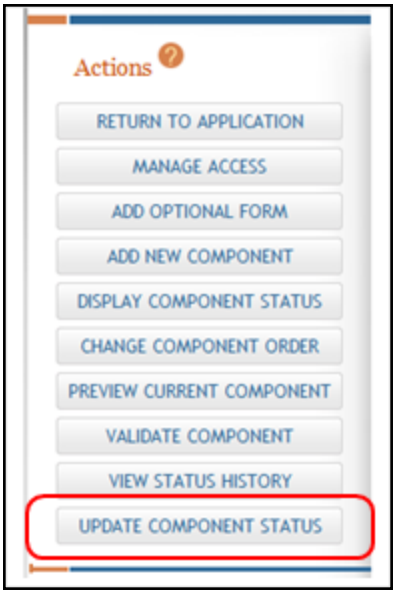
1. From the *Application Information* page select the **Update Submission Status** button from the **Action** list on the left side of the screen.
   The *Update Status* window displays.
2. Select the *Work in Progress* status from the **Select Status** drop-down list.



3. Complete the status update:
   a. Enter a comment in the provided text box.
   b. Select the **Add comment** button.
      -OR-
   c. Select the link titled **or continue without adding a comment** to update the status without entering a comment in the provided text box.

4. Select the component needing revision from the Component Type section of the page.

5. Select the Update Component Status button from the **Actions** section of the page.



6. Update the status of the component to *Work in Progress* by selecting it from the drop-down box, entering comments, and selecting the **Add Comment** button.

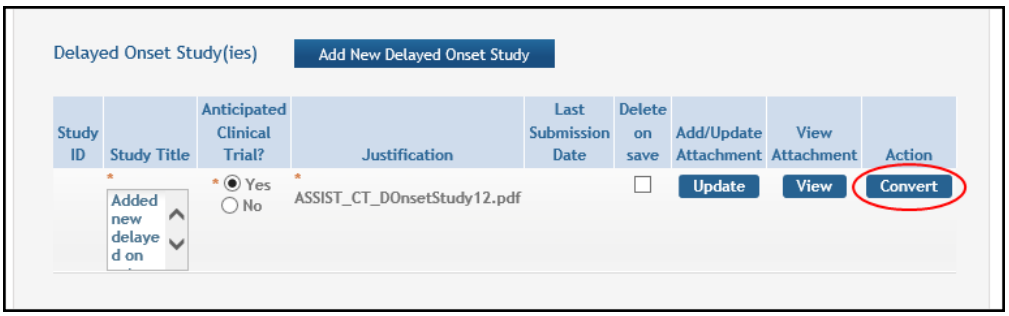
Once the status of the component is *Work in Progress*, the appropriate component form(s) can be updated. Navigate to the appropriate forms, make the changes, and re-submit the application. Refer to the help topic titled Submit the Application for information on submitting the application.

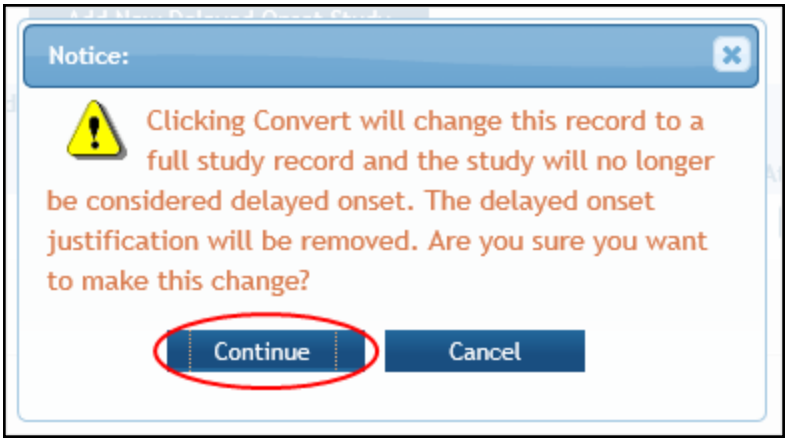
NOTE: Only the signing official (SO) can submit the application to NIH.

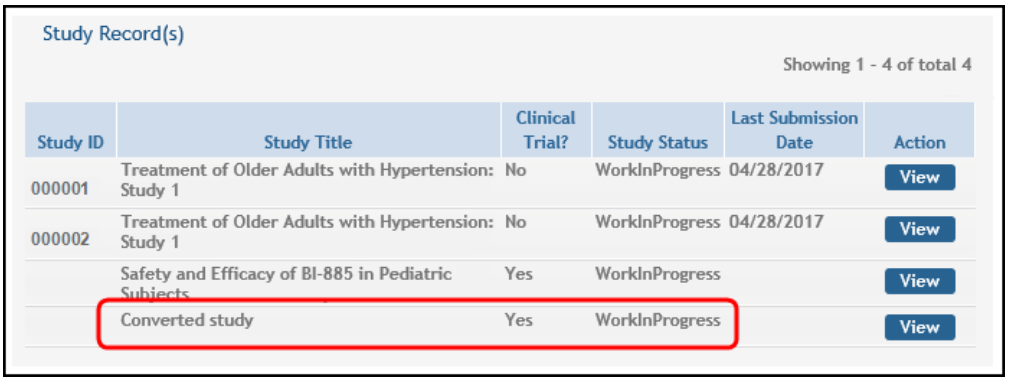
6.1 Convert Delayed Onset to Full Study Record

6.1.1 Flow:

1. Click on the **Edit** Button
2. Click the **Convert** button – the system displays following warning:
   a. Clicking "Convert" will change this record to a full study record and the study will no longer be considered delayed onset. The delayed onset justification will be removed. Are you sure you want to make this change?"
3. If you choose the **Cancel** option, you will stay on the *Post Submission* screen and the Delayed Onset remains as Delayed Onset
4. If you choose the **Continue** option you will be taken to the *Study Page* with title populated and rest of the fields empty.
5. Select **Save** (and keep or release lock) after completing the fields on the *Study Page*.
6. The action of saving the study removes the study from the *Delayed Onset Study* table and a new study is saved and added to the *Study Record* table.







Study Record(s)

Showing 1 - 4 of total 4

Study ID	Study Title	Clinical Trial?	Study Status	Last Submission Date	Action
000001	Treatment of Older Adults with Hypertension: Study 1	No	WorkInProgress	04/28/2017	View
000002	Treatment of Older Adults with Hypertension: Study 1	No	WorkInProgress	04/28/2017	View
	Safety and Efficacy of BI-885 in Pediatric Subjects	Yes	WorkInProgress		View
	Converted study	Yes	WorkInProgress		View

7.1 Study Statuses

A status will be maintained for each study version. There will be two primary values used:

Received by Agency: any new study version will have this status. Studies that initially come in on initial submission will have this status, and any post-submission of the study will have this status.

Accepted: when an award occurs, any studies for which the awarded project is the primary project will have this status. The latest version will also be labeled with the relevant FY of the award.

NOTE: The Status of a study version on a contract application should always be set to "Accepted".

8.1 When Should I Access HSS via the Status Module?

HSS is used to view and maintain inclusion data associated with your grant(s) and can be accessed in one of two ways, both through the eRA Commons system: via the **Status** module –or– via the RPPR **Section G. Special Reporting Requirements**.

8.1.1 When to Use the Status Module Instead of RPPR

There are several reasons why you might need to access inclusion data through Commons Status rather than through your progress report. For example:

- Before award of a competitive application, changes may be necessary to the inclusion data submitted with the application via Grants.gov.
- Post-award, there may be a requirement to provide more frequent updates to inclusion enrollment in addition to any reporting associated with the RPPR.

Inclusion data cannot always be updated using Status. When application is undergoing peer review, the inclusion data is not accessible in the *Human Subjects System*. Also, after a grant is awarded, only the **View** links will be available for the IERs associated with fiscal year award. The data for a given fiscal year is locked when the award is issued and no further updates can be made. At that point, you can make updates via Status for the record associated with the next fiscal year.

For details on using the Status module for accessing HSS, please refer to Access HSS. You can also access the HSS Online Help by selecting the help icons ('?') on any of the HSS screens.

8.1 Roles & Privileges

8.1.1 HSS ROLES & PRIVILEGES:

Below are the roles and associated privileges pertinent to managing studies and projects in HSS.

	Principal Investigator	Signing Official
View study records	X	X
Receive notifications		X
Edit all HSCT and IER fields (except HS exemption and clinical trial code)	X	X
Initiate study record submission	X	X
Submit study record		X

8.1 Additional Resources (HSCT form and more)

HSS relies on information from more than one source and not all information provided in the HSS online help and PDF guides is exhaustive. Below are links to additional resources to provide

greater detail and explanation on the various topics and systems related to HSS.

- HSCT form in ASSIST
  - Basic Information (Study Record - Section 1)
  - Study Population Characteristics (Study Record - Section 2)
  - Protection and Monitoring Plans (Study Record - Section 3)
  - Protocol Synopsis (Study Record - Section 4)
  - Other Clinical Trial-related Attachments (Study Record - Section 5)
  - Inclusion Enrollment Report
  - Participant Level Data Collection
- ASSIST (online help) - HSS leverages ASSIST screens and therefore has the same look and feel.
- HSS Training - Contains links to user guide, video tutorials, IMS to HSS Crosswalk, and infographic of the HSS process
- How to Apply - Application Guide - Use application instructions, along with guidance in the funding opportunity announcement, to submit grant applications to NIH, CDC, FDA and AHRQ.